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B5. 21. (Amended) A breast implant comprising a self-expanding matrix of biocompatible material, the expanded matrix having a porous structure for supporting surrounding tissue of a breast and [providing] configured to provide a framework for the in-growth of fibrous tissue into the matrix.

✓ Please add new claim 25 as follows:

21. 25. The implant of claim 1, wherein the outer shell is adjacent the inner core.

REMARKS

Claims 1-3 and 5-24 were pending. Claims 1, 6, 10, 16-19, and 21 have been amended. Claim 25 has been added. Claim 11 has been canceled.

Claims 1-3, 5-6, 10, and 16-19 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,298,998 to Naficy. Claims 7-9, 11, 14, 15, and 20-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Naficy in view of U.S. Patent No. 6,066,325 to Wallace et al. Applicants respectfully traverse the rejections.

A. Request for Reconsideration of Final Rejection:

Applicants respectfully request reconsideration and withdrawal of the finality of the Office action as premature pursuant to MPEP § 706.07. MPEP § 706.07(a) states that second actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is not necessitated by Applicants' amendment of the claims. Applicants submit that at least two new grounds of rejection have been introduced by the Examiner in the second Office action that were not necessitated by Applicants' amendment of the claims, as follows:

1) Claim 6 was indicated as being allowable in the first Office action, subject to its dependence on rejected base claim 1. Accordingly, Applicants rewrote claim 6 in independent form as claim 18. The scope of claim 18 is identical to that of original claim 6. In the second action, the Examiner improperly has rejected claim 18 under 35 U.S.C. § 102(b) as being anticipated by the newly-cited reference to Naficy. The Examiner's assertion in paragraph no. 9

of the second Office action that the new ground of rejection was necessitated by Applicants' amendment is unfounded, since the scope of claim 18 is identical to that of originally allowable claim 6. Accordingly, the finality of the rejection should be withdrawn.

2) The Examiner unnecessarily has introduced new grounds of rejection in the second action based on the newly-cited patent to Wallace et al. Wallace et al. has been cited in the second action as disclosing medicinal drugs; however, medicinal drugs were established by the claims as originally filed, and Liu et al. was cited in the first action as teaching medicinal drugs. Applicants' amendment did not introduce medicinal drugs into the claims or otherwise alter the scope of the claims so as to necessitate citing a new reference to teach medicinal drugs. The introduction of the newly-cited reference to Wallace et al., which issued on May 23, 2000, appears to have been based on availability, and not on any need to address Applicants' amendment.

For the reasons above, withdrawal of the finality of the Office action is fair and proper, will prevent piecemeal prosecution of the application, and will allow Applicants to respond fully to the new grounds of rejection. Reconsideration and withdrawal of the final rejection respectfully is solicited.

B. Prior Art Rejections under 35 U.S.C. §§ 102(b) and 103(a):

The present invention as recited in amended claim 1 is an implant for implantation in a human body. The implant has an outer shell of resorbable material and a resorbable inner fluid core. The implant is formed to fit the shape and size of a cavity in the human body, and is configured to be installed for supporting tissue surrounding the cavity and allowing in-growth of fibrous tissue into and replacing the outer shell.

In contrast to the present invention as recited in amended claim 1, Naficy discloses a two-phase breast prosthesis having two shells: an outer shell and a non-absorbable inner shell. The non-absorbable inner shell is made of silicone rubber, for example. See col. 9, lines 21-27. Accordingly, Naficy does not teach an implant having a resorbable inner core and does not anticipate the present invention as recited in amended claim 1.

Wallace et al. does not cure the deficiencies of Naficy. Wallace et al. discloses hydrogel

components used for controlled-release drug delivery and filling tissue defects. Wallace et al. does not teach or suggest an implant having a resorbable inner core.

Claim 1 as amended is submitted to be patentable over the cited prior art. Claims 2, 3, 5-9, 16-17, and 25, being dependent on claim 1, similarly are submitted as being patentable over the cited prior art. Claim 18 has been amended to recite a resorbable inner core, and for the reasons noted above also is submitted, along with dependent claim 19, as being patentable over the cited reference.

The present invention as recited in amended claim 10 is a method for replacing excised human breast tissue with an implant. The method includes forming a cavity having surrounding tissue within a breast. The implant is formed entirely of resorbable material, and is sized to occupy the cavity. The implant supports the surrounding tissue and allows for in-growth of fibrous tissue into and replacing the resorbable material.

In contrast to the present invention as recited in amended claim 10, Naficy discloses an implant having a non-absorbable inner core. Consequently, Naficy does not anticipate the present invention as recited in claim 10, and claim 10 is submitted as being allowable over the cited reference. Further, as noted above, Wallace et al. does not teach or suggest an implant having a resorbable inner core, and thus does not cure the deficiencies of Naficy with respect to amended claim 10. Claim 10 and its dependent claims 11, 14, 15, and 20 are submitted as being patentable over the cited references.

The present invention as recited in amended claim 21 is a breast implant including a self-expanding matrix of biocompatible material, the expanded matrix having a porous structure for supporting surrounding tissue of a breast and configured to provide a framework for the in-growth of fibrous tissue into the matrix.

In contrast to the present invention as recited in amended claim 21, Naficy discloses a two-phase breast implant having an outer shell and an inner, non-absorbable inner shell. Naficy does not teach or suggest a breast implant having a self-expanding matrix of biocompatible material. Wallace et al. does not cure the deficiencies of Naficy. Wallace et al. discloses hydrogel components used for controlled-release drug delivery and filling tissue defects. Wallace et al. discloses that the hydrogel has "flowability" sufficient that the material can be

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injected through a syringe. In addition, the hydrogel can be used in a partially-hydrated form and allowed to swell in situ by absorbing water from a moist environment. See, *inter alia*, col. 5, lines 43-46 and col. 9, lines 61-64. Wallace et al. does not disclose or suggest, however, that the hydrogel is self-expanding. Applicants respectfully disagree, therefore, with the Examiner's contrary assertion in paragraph no. 6 of the second action. On the contrary, it appears that the Examiner is reading characteristics into the Wallace et al. reference based on a hindsight attempt improperly to reconstruct the present invention based on Applicants' disclosure. Moreover, Wallace et al. does not teach or suggest an expanded matrix having a porous structure as recited in amended claim 21. In view of the amendments and remarks above, claim 21 and dependent claims 22-24 are submitted as being patentable over the cited references.

The application is submitted as being in condition for allowance.

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Name of Person Mailing Correspondence

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October 19, 2000

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